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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/506,664	05/02/2005	Andrzej Czemecki	POL0005-PCT	5014
28970	7590	03/16/2006	EXAMINER	
PILLSBURY WINTHROP SHAW PITTMAN LLP 1650 TYSONS BOULEVARD MCLEAN, VA 22102			TOWA, RENE T	
			ART UNIT	PAPER NUMBER
			3736	

DATE MAILED: 03/16/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	Application No.	Applicant(s)	
	10/506,664	CZERNECKI ET AL.	
	Examiner	Art Unit	
	Rene Towa	3736	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-4 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-4 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 03 September 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All    b) ☐ Some \* c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                        | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)               | Paper No(s)/Mail Date. ____.  |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date <u>09/03/04</u> .  | 6) <input type="checkbox"/> Other: ____.                                    |

## DETAILED ACTION

### *Priority*

1. Receipt is acknowledged of papers submitted under 35 U.S.C. 119(a)-(d), which papers have been placed of record in the file.

### ***Claim Rejections - 35 USC § 102***

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

3. Claim 1 is rejected under 35 U.S.C. 102(e) as being anticipated by Rutynowski et al. (US Patent No. 6,613,064).

In regards to claim 1, Rutynowski et al. disclose a device for puncturing patient's skin comprising a sleeve 1, a push element 2 mounted on one end of the sleeve 1, a piston 5 with puncturing tip 8 slidably mounted inside the sleeve 1, and a drive spring 10 positioned between the face of the push element 2 and the piston 5, characterized by that at the other end of the sleeve 1 an indicating-adjusting member 3, comprising an opening 4 for the puncturing tip 8 and comprising inwardly directed stair shaped limiting members, which are capable of being hit in operation by the fin 7 of the piston 5, is mounted turnably with respect to the axis of the sleeve, wherein the indicating-adjusting

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member 3 has at least one indicator 16 of the pre-set puncturing depth 17 located in a circumferential groove in the lower part of the sleeve 1 with external cut-outs (see figs. 1-2; column 2/lines 1-7; see claim 3).

4. Claims 1-2 are rejected under 35 U.S.C. 102(b) as being anticipated by Bodicky et al. (US Patent No. 4,895,147).

In regards to claim 1, Bodicky et al. disclose a device for puncturing patient's skin comprising a sleeve 12, a push element 20 mounted on one end of the sleeve 12, a piston 16 with puncturing tip 74 slidably mounted inside the sleeve 12, and a drive spring 34 positioned between the face of the push element 20 and the piston 16, characterized by that at the other end of the sleeve 12 an indicating-adjusting member 13, comprising an opening for the puncturing tip 74 and comprising inwardly directed stair shaped limiting members 58, which are hit in operation by the fin 48 of the piston 16, is mounted turnably with respect to the axis of the sleeve 12, wherein the indicating-adjusting member 13 has at least one indicator 60 of the pre-set puncturing depth located in a circumferential groove 50 in the lower part of the sleeve 12 with external cut-outs (see figs. 1-2; column 4/lines 17-24).

In regards to claim 2, Bodicky et al. disclose a device for puncturing patient's skin wherein the external cut-outs in the sleeve 12 have different widths (see fig. 1).

***Claim Rejections - 35 USC § 103***

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the

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invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. Claim 3 is rejected under 35 U.S.C. 103(a) as being unpatentable over Bodicky et al. ('147) in view of Harding (5,613,978).

In regards to claim 3, Bodicky et al. disclose a device for puncturing patient's skin comprising a sleeve 12, a push element 20 mounted on one end of the sleeve, a piston 16 with puncturing tip 74 slidably mounted inside the sleeve 12, and a drive spring 34 positioned between the face of the push element 20 and the piston 16, characterized by that the push element 20 comprises a turnably mounted therein puncturing force adjusting member 13.

Bodicky et al. do not disclose a force-adjusting member, which comprises inwardly directed pair of oblique half-ring members pressing the push rod of the piston in operation.

However, Harding discloses a force-adjusting member, which comprises inwardly directed pair of oblique half-ring members (50, 60) (see fig. 10).

It would have been obvious to one of ordinary skill in the art at the time Applicant's invention was made to provide a puncturing device similar to that of Bodicky et al. with a pair of oblique half-ring members similar to those of Harding in order to provide a smooth or continuous lancet penetration depth.

7. Claim 4 is rejected under 35 U.S.C. 103(a) as being unpatentable over Bodicky et al. ('147).

Bodicky et al. disclose a device for puncturing patient's skin comprising a sleeve 12, a push element 20 mounted on one end of the sleeve 12, a piston 16 with

puncturing tip 74 slidably mounted inside the sleeve 12, and a drive spring 34 positioned between the face of the push element 20 and the piston 16.

Bodicky et al. does not disclose a push element comprising a turnably mounted therein puncturing force adjusting member (38), which comprises inwardly directed stair shaped members. However, shifting the location of the stair shaped member from one end of the sleeve to another is a design choice that has previously been held to be unpatentable, see *In re Japikse*, 181 F.2d 1019, 1023, 86 USPQ 70, 73 (CCPA 1955).

It would have been obvious to one of ordinary skill in the art at the time Applicant's invention was made to provide a puncturing device similar to that of Bodicky et al. with a push element comprising a stair shaped member in order to provide graded lancet penetration depths.

### ***Conclusion***

8. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

US Patent No. 6,248,120 to Wyszogrodzki discloses a puncturing device comprising a sleeve, a push element and a piston.

US Patent No. 5,356,420 to Czernecki et al. discloses a device for puncturing comprising a sleeve, a push-button, a piston and a spring.

US Patent No. 5,730,753 to Morita discloses an assembly for adjusting pricing depth of lancet.

US Patent No. 4,503,856 to Cornell et al. discloses a lancet injector comprising a tubular housing and a slidable lancet.

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US Patent No. 6,210,420 to Mauze et al. discloses an apparatus and method for efficient blood sampling with lancet.

US Patent No. 6,066,103 to Duchon et al. discloses a body fluid sampling device for a skin incision.

US Patent No. 6,053,930 to Ruppert discloses a single use lancet assembly.

US Patent No. 6,022,366 to Schraga discloses a lancet having adjustable penetration depth.

US Patent No. Re 32, 922 to Levin et al. discloses a blood sampling instrument.

US Patent No. 6,645,219 to Roe discloses a rotatable penetration depth adjusting arrangement.

US Patent No. 6,451,040 to Purcell discloses an adjustable endcap for lancing device.

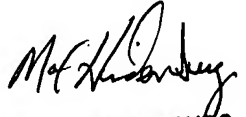
9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Rene Towa whose telephone number is (571) 272-8758. The examiner can normally be reached on M-F, 8:00-16:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on (571) 272-4726. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

RTT

  
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